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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,652	12/12/2003	Anuj Bellare	1407.1037-009	8950
21005	7590	08/22/2006	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			YOON, TAE H	
			ART UNIT	PAPER NUMBER
			1714	

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/734,652

Applicant(s)

BELLARE ET AL.

Examiner

Tae H. Yoon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Updated continuing data (US Pat. No. 6,689,823) for the application 09/541,374

In line 5 of page 1 is needed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 6,689,823.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the solid filler of said patent encompasses the instant nanoencapsulated solid filler since there is no structural limitation to said solid filler in said patent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recited "less than about (1000 nanometers, for example)" is indefinite. It has to be either "less than" or "about". See *Amgen, Inc. V. Chugal Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (fed. Cir. 1991).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 14 and 16-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Podszun (US 4,617,327).

Podszun teaches the instant composition in example 4 wherein the use of coated (or encapsulated) silica filler having a particle size of 20 nm in methyl methacrylate and polymethyl-methacrylate polymer bead is seen. Said composition can be a surgical cement and used in making a surgical material having an average matrix ligament

thickness of less than about 1000 nanometers inherently since said silica filler has a particle size of 20 nm. Podszun teaches that DE-OS 2,403,211 and 2,462,271 teach microfine silicon dioxide (microfiller) with a particle size of 5 to 700 nm at col. 1, lines 26-32. Podszun further teaches replacing said microfiller particles with microfiller-containing prepolymers at col. 1, lines 39-53, and thus the "microfillers" taught at col. 2, lines 3-7 inherently refers to said 5 to 700 nm of DE-OS.

Thus, the invention lacks novelty.

Claims 1-8, 14, 16-19, 21 and 22 are rejected under 35 U.S.C. 103(a) as obvious over Podszun (US 4,617,327).

The instant invention further recites a powder composition over Podszun who teaches a mixture of powder form of a nanoencapsulated solid filler and PMMA bead polymer and methacrylate monomers in example 4.

It would have been obvious to one skilled in that at the time of invention to store said powder and monomers in separate packages until use since such packages would provide easy mixing of various ratios of said powder and monomers.

Claims 1-8 and 15-22 are rejected under 35 U.S.C. 103(a) as obvious over Podszun (US 4,617,327) and Franz et al (US 5,797,873).

The instant invention further recites radio-opaque solid filler over Podszun who teaches employing metal oxides at col. 2, lines 19-26. Franz et al teach said radio-opaque solid filler at col. 5, line 27 and col. 6, line 45 (zirconium dioxide).

It would have been obvious to one skilled in that at the time of invention to utilize said zirconium dioxide of Franz et al in Podszun since Podszun teaches employing metal oxides and since the use of radio-opaque solid filler in polymeric compositions for medical applications in order to check the repaired part of a human body such as bone or teeth with X-ray machine is a routine practice in the art.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as obvious over Franz et al (US 5,797,873) in view of Mathiowitz et al (US 6,143,211) and Jiang et al (US 5,847,046).

Franz et al teach a process for the preparation of bone cement comprising a polymeric powder, X-ray contrast media and filler having a particle size of below 100 μm and acrylic monomers in abstract and example and at col. 4, lines 53-60 and col. 5, lines 20-37. Said particle size of below 100 μm encompasses nanometers. Radio-opaque solid fillers such as hydroxyl-apatite and zirconium dioxide are seen in example. Franz et al also teach a prepolymerized implant or bone cement at col. 6, lines 5-13.

The instant invention further recites nanoencapsulated filler and biodegradable polymer matrix over Franz et al. However, the use of a biodegradable polymer matrix such as polylactic acid or polyglycolic acid in implants is well known as taught by Jiang et al, abstract and col. 3, lines 20-40. Mathiowitz et al teach nano- and micro-encapsulated filler at col. 5, lines 1-10 and in table 3 and its use in pharmaceutical applications in examples 2 and 3. Mathiowitz et al teach the advantage (such as instant or controlled release on a site) of using nanoencapsulated filler at col. 1, lines 11-23.


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It would have been obvious to one skilled in that at the time of invention to utilize said nanoencapsulated filler of Mathiowitz et al in Franz et al since Franz et al teach employing particle size of below 100 μm encompassing nanometers and since Mathiowitz et al teach the advantage (such as instant or controlled release on a site) of using nanoencapsulated filler, and further to utilize a biodegradable polymer matrix taught by Jiang et al in Franz et al and Mathiowitz et al thereof since the use of a biodegradable polymer matrix such as polylactic acid or polyglycolic acid in implantable drug depots is well known as taught by Jiang et al absent showing otherwise.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tae H. Yoon whose telephone number is (571) 272-1128. The examiner can normally be reached on Mon-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Tae H Yoon
Primary Examiner
Art Unit 1714

THY/August 17, 2006